

REMARKS

Status of the Claims

Claims 1-19 and 22-49 are currently pending in the application. Claims 19-23 stand rejected. Claims 1-18 and 24-49 are withdrawn as being drawn to a non-elected invention. Claims 19, 22 and 23 have been amended as set forth herein. Claims 20 and 21 have been cancelled herein. All amendments and cancellations are made without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendment of the claims to recite “suppressed” is supported, for example, by claims 17 and 18 as originally filed. Amendment of the claims to be directed to Chinese hamster cells is supported at least by original claim 21, now cancelled. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 101

Claims 19-23 stand rejected under 35 U.S.C. § 101 because they allegedly are directed to non-statutory subject matter. (*See*, Office Action of October 10, 2007, at pages 3-4, hereinafter, “Office Action”). Claims 20 and 21 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that “the claimed invention is directed to non-statutory subject matter” because the claims encompass products of nature. (*Id.* at page 4). Applicants have amended the claims to recite “isolated” cells, as suggested by the Examiner.

Reconsideration and withdrawal of the rejection of claims 19, 22 and 23 are respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 19-23 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (See, Office Action, at page 4). Claims 20 and 21 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that the term “disrupted” is indefinite. (*Id.*).

Although Applicants do not believe that the claims are indefinite, to expedite prosecution, the term “disrupted” has been replaced by the term “suppressed.” The amendment clarifies that the expression of the gene is suppressed. This amendment is supported, for example, by claims 17 and 18 as originally filed.

Reconsideration and withdrawal of the indefiniteness rejection of claims 19, 22 and 23 are respectfully requested.

Rejections Under 35 U.S.C. § 102(b)

Claims 19, 20 and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Luhn et al., *Nature Gen.*, 28:69-72, 2001 (hereinafter referred to as “Luhn et al.”). (See, Office Action, at pages 4-5). Claim 20 has been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to claim 20. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that Luhn et al. disclose cloning of 12 cDNAs from *C. elegans*, "encoding multi-spanning transmembrane proteins with homology to known nucleotide sugar transporters," and transfecting these into fibroblasts from an LAD II patient. (*Id.* at page 5).

Although Applicants do not agree that the claims are anticipated by the disclosure of Luhn et al., to expedite prosecution, claims 19 and 23 have been amended herein without prejudice or disclaimer to be directed to Chinese hamster cells. Luhn et al. do not disclose the use of Chinese hamster cells.

Therefore, Luhn et al. do not disclose all of the limitations of the presently claimed invention. Anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (See, *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1990), quoting *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)).

Reconsideration and withdrawal of the anticipation rejection of claims 19 and 23 are respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 19-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Luhn et al. in view of Kao et al., *PNAS USA*, 60:1275-1281, 1968 (hereinafter, "Kao et al."). (See, Office Action, at pages 5-6). Claims 20 and 21 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that Luhn et al. disclose the gene, which is defective in leukocyte adhesion deficiency II (LAD II), and which encodes a putative GDP-fucose transporter. That is, Luhn et al. disclose a cell deficient in a fucose transporter gene. (*Id.* at page 6). The Examiner further states that Kao et al. disclose a CHO cell that was used for cloning purposes. Therefore, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to design a cell wherein the fucose transporter gene is disrupted and a vector is used to disrupt a fucose gene, as taught by Luhn et al., and to further use a Chinese hamster cell to apply the gene targeting vector disclosed in Kai et al.

However, it is respectfully submitted that the Examiner misinterprets the disclosure of Luhn et al. Luhn et al. discloses only the following:

- (i) An isolated cell from a patient suffering from leukocyte adhesion deficiency II, which has a mutation in ORF-7 which encodes a fucose transporter;
- (ii) It is assumed that the leukocyte adhesion deficiency II is caused by the deficiency of the fucose transporter function; and
- (iii) When a normal ORF-7 is forced to be expressed in the cell, the fucose addition reaction is able to return to normal.

Accordingly, Luhn et al. disclose that the disease can be treated by expressing the fucose transporter gene normally, not by suppressing the function of the fucose transporter.

This is supported by, for example, the description of Luhn et al., stating that “expression of this transporter in LAD II cells rescues the fucosylation defect.” (See, Luhn et al., at lines 2 to 3, left column, page 71). Luhn et al. further state that “Transient co-transfection of LAD II cells

with full-length human ORF-7 and a GFP marker re-established fucosylation in all of the GFP-positive cells." (Luhn et al., at lines 5 to 8, left column, page 71).

Therefore, one of ordinary skill in the art would be motivated to force the normal fucose transporter gene to express based on the disclosure of Luhn et al. Luhn et al. cannot motivate one of ordinary skill in the art to suppress the expression of the fucose transporter gene. Luhn et al. do not disclose or suggest artificial suppression of the fucose transporter gene.

Furthermore, the disclosure of Kao et al. fails to cure this defect in the disclosure of Luhn et al. Kao et al. disclose a nutritional mutant only. Kao et al. neither disclose the claimed cell of the present application nor the LAD II cells disclosed in Luhn et al.

Therefore, Luhn et al. actually teach away from the presently claimed invention. A reference which leads one of ordinary skill in the art away from the claimed invention cannot render it unpatentably obvious. (*See, Dow Chem. Co. v. American Cyanamid Co.* 816 F2d 617, (CAFC 1987)). In determining the scope and content of the prior art, and determining whether the prior art suggested the claimed invention, the references "must be read as a whole and consideration must be given where the references diverge and teach away from the claimed invention." (*See, Akzo N.V. v. United States Int'l Trade Comm'n*, 1 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1986); *In re Fine*, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988)).

Finally, because of this lack of disclosure in the cited references, and due to the fact that the references actually teach away from the presently claimed invention, there is no motivation to combine the disclosures of Luhn et al. and the disclosures of Kao et al. as indicated by the Examiner. Consequently, the claimed inventions of the present application are not obvious over Luhn et al. and Kao et al.

Thus, reconsideration and withdrawal of the obviousness rejection of claims 19, 22 and 23 are respectfully requested.

CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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